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be issued a "do not recommend" decision than non-oncology reviews (56% vs. 16%, p<. 001). Over time, there was no significant trend in rates of "do not recommend" decisions for non-oncology reviews and oncology reviews, though rates of "do not recommend" decisions have increased for oncology reviews since 2008. There were no differences in the rates of "recommend" and "recommend with restriction" decisions between oncology and non-oncology reviews (p=. 87). Over time there was a significant decrease in the rates of "recommend with restrictions" decisions for oncology reviews (p=. 07), but no statistical trend in non-oncology reviews. **CONCLUSIONS:** NICE was more likely to issue a "do not recommend" decision for oncology reviews than for non-oncology reviews, but there was no difference in the overall rates of "recommend with restrictions" decisions. Over time, NICE appears to be replacing "recommend with restriction" decisions with "do not recommend" decisions in oncology reviews, but this did not pass traditional significance levels.

PCN264

SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS IN CANCEROLOGY IN BRAZIL BETWEEN 1980 AND 2013

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Nowadays, economic evaluation has been increasingly used in health care decision-making in Brazil. The Brazilian economic evaluation literature in cancerology is unknown. **OBJECTIVES:** This systematic review aims to identify and characterize the economic evaluation studies in cancerology conducted in Brazil. **METHODS:** Ten online databases (MEDLINE (PubMed), EMBASE, Latin American and Caribbean Literature on Health Sciences Database (LILACS), Scientific Electronic Library Online (SciELO), NHS Economic Evaluation Database (NHS EED), HTA Database (Centre for Reviews and Dissemination (CRD)), Biblioteca Virtual em Saúde Economia da Saúde (BVS ECOS), SCOPUS, Web of Science, and the Sistema de Informação da Rede Brasileira de Avaliação de Tecnologias em Saúde (SISREBRATS) were systematically searched. We also performed manual search. We selected partial and full economic evaluation studies in cancerology, where at least one of the authors was affiliated to a Brazilian institution. Two authors performed study selection and data extraction independently. Disagreements were resolved through discussion or through consultation with a third reviewer. The study characteristics were summarized in figures and summary tables. **RESULTS:** A total of 11946 records were identified. Fifty six articles met inclusion criteria, of these, 33 (59%) were a full and 23 (41%) were a partial economic evaluation. The cost-effectiveness analysis was the most used (27%). There was an increase in the number of publications over the years, especially after 2006. Researchers from the Southeast region of Brazil were responsible for the majority of the publications (82%). Cancers most frequently studied were breast cancer (37%), followed by cervical cancer (16%), lung cancer (12%) and colorectal cancer (9.0%). The technologies most studied were medications (34%). **CONCLUSIONS:** The expansion of the economic analysis literature could be explained by the growing demand for HTA studies by the National Policy for Health Technology Assessment in Brazil that may have stimulated the scientific production in this area.

PCN265

HEALTH TECHNOLOGY ASSESSMENTS IN ONCOLOGY: CRIZOTINIB CASE STUDY

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OBJECTIVES: Crizotinib (Xalkori®) was approved for the treatment of adults with non-small cell lung cancer (NSCLC). The objective of this study was to illustrate the divergence of Health Technology Assessments in oncology by comparing the decisions of the National Institute for Health and Care Excellence (NICE), the Federal Joint Committee (G-BA) and French National Authority for Health (HAS). **METHODS:** Crizotinib's pivotal trial (Study 1007) was analysed. NICE, G-BA and HAS reports were reviewed, decisions' drivers identified and final decisions compared. **RESULTS:** Study 1007 was a randomised open-label trial comparing crizotinib with chemotherapy in patients with ALK+ advanced NSCLC and who had failed one chemotherapy regimen. The primary endpoint was progression-free survival (PFS) and overall survival (OS) was a secondary endpoint. While treatment with crizotinib increased significantly the PFS (4.7 months) no significant improvement in OS was observed versus chemotherapy group (OS interim analysis). Some quality of life (QoL) items (e.g. chest pain, dyspnea, fatigue) were improved within the crizotinib group. Even though no improvement in the OS was shown, the G-BA assessed the crizotinib benefit as considerable based on the improvement of QoL and morbidity decrease. The HAS also granted crizotinib an improvement in actual benefit of III based on the improvements in the PFS and QoL. However, the significant gain in PFS was not sufficient to get positive guidance from NICE. Indeed, NICE did not recommend the use of crizotinib due to the uncertainties surrounding the OS: interim OS data and high rate of patients "crossing-over" from standard therapy to crizotinib arm. **CONCLUSIONS:** Cross-over has become a real obstacle to appreciate oncology product value. While an additional benefit can be granted based on improvement in PFS plus morbidity and QoL results in Germany and France, products supported solely by an increased PFS and no change in OS may face access barriers in England.

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IMPACT OF HEALTH CARE REFORM ON DRUG REIMBURSEMENT DECISION-MAKING IN TAIWAN

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OBJECTIVES: Taiwan is considered a challenging market to access, largely due to strict pricing and reimbursement policies. To assess the impact of health insurance reforms introduced in January 2013 (Second Generation National Health Insurance or 2GNHI), Taiwan reimbursement decisions and granted prices before and after the introduction were compared with major western countries. **METHODS:** Publications of Taiwan NHI from March 2011 to February 2014 were searched and reimbursement decisions identified. The largest therapy areas, oncology and cardiovascular, which accounted for 40% of decisions, were compared with those of three major HTA agencies: CADTH, NICE and PBAC. HTA reports and meeting transcripts were analysed and categorised by date, therapy area, decision, rationale, and pricing decision. Resubmissions or those not assessed by the western HTA agencies were excluded. **RESULTS:** A total of 65 NHI reports were identified. Of these 26 reported decisions on oncology or cardiovascular drugs, 12 were excluded (3 resubmissions, 9 not reviewed by the other agencies). Prior to 2GNHI, 4 out of 5 decisions were positive, or 80% approval rate, while after, only 4 out of 9 were positive, a 44% approval rate. Prior to 2GNHI, all NHI reimbursement decisions identified (6) matched CADTH, NICE, and PBAC. After 2GNHI, only 6/9 or 66% matched. Clinical effectiveness and budget impact were most cited in reimbursement rejections. For example Zytiga, NHI appreciated the cost-effectiveness but stated budget impact was too high, issuing a negative recommendation, contrary to the other agencies. Interestingly, a 'local' product was recommended for limited reimbursement even though budget impact was high. **CONCLUSIONS:** Since implementation of Taiwan's NHI reforms in January 2013, cardiovascular and oncology drug approvals dropped by 36% and agreements with western agencies down 34%, placing an emphasis on budget impact. However, this analysis was constrained by its small sample size, and limited therapy areas.

PCN267

EXPANDED DATA SETS FOR HTA DECISION-MAKING IN ONCOLOGY: DO THEY HELP TO ACHIEVE POSITIVE APPRAISALS?

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OBJECTIVES: Phase III, randomised controlled trials remain the gold standard for health technology assessment (HTA) submissions. Data sets may be supplemented with other sources (e.g. Phase II trials, observational studies, mixed treatment comparisons). However, the influence of expanded data sets on HTA appraisals is unclear. **METHODS:** We reviewed recent National Institute for Health and Care Excellence (NICE; England and Wales) oncology drug submissions to determine the frequency and type of expanded data sets. We then evaluated the influence of expanded data on agency decisions. A similar review of submissions to the Australian Pharmaceutical Benefits Advisory Committee (PBAC) was performed. **RESULTS:** There were 30 relevant appraisals on the NICE website covering a range of cancer types. Of these, 14/30 made use of expanded data sets featuring Phase II trials, observational studies, meta-analyses and/or mixed treatment comparisons among other sources. Reasons for using expanded data sets included: agency concerns over Phase III studies, lack of long-term or head-to-head data and limited Phase III data. Where additional data were included, around one third (5/14 cases, 35.7%; 5/30 [16.7%] overall) appeared to have directly influenced the final decision. Overall, positive appraisals were less frequent for submissions that featured expanded data sets compared with submissions featuring Phase III data only (2/14 [14.3%] versus 9/16 [56.3%]). Comparable to NICE, 2/10 (20%) of PBAC submissions were influence by expanded data sets, although cost-effectiveness data were crucial for PBAC approval overall. **CONCLUSIONS:** We found that expanded data sets feature in nearly half of recent NICE oncology HTA assessments. However, additional data appeared to influence only one in five appraisals by NICE and PBAC. Expanded data sets have a place in contributing to HTA decision making, but overall, rigorous Phase III RCT data remain essential to obtaining a positive HTA appraisal.

PCN268

THE LIFE AND DEATH OF THE END OF LIFE TREATMENT APPRAISAL CRITERIA IN NICE TECHNOLOGY APPRAISALS?

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OBJECTIVES: Since January 2009, NICE in the UK allows end of life (EOL) treatments to exceed the upper end (£30,000/QALY) of the threshold range for incremental cost-effectiveness ratios (ICERs) by using higher weights for EOL life-years. With discussions surrounding the concept and implementation, and the introduction of the value based assessment framework, the aim of this study was to review NICE technology appraisals (TAs) in oncology to assess the interpretation, implementation and implications of the criteria. **METHODS:** All completed TAs in oncology since 2009 were searched. When multiple submissions of the same TA were made, the latest were selected. Data were extracted to capture details of the appraisal (e.g. treatment, indication and decision), the consideration of the five different EOL criteria (applicability, interpretation, effect on the decision) and the method of implementation (weighting, threshold). **RESULTS:** 61 TAs, including six multiple technology appraisals, assessing 71 technologies were reviewed. EOL criteria were considered in 40 TAs covering 44 technologies. EOL weighting was considered appropriate for 36% of technologies. Most technologies fulfilled the criterion of <24 month life expectancy (rejected in 14%), extension of life by ≥3 months or robustness of its calculation was the most common cause of rejection (32%/25% respectively). These criteria were inconsistently applied, using different methods (e.g. medians, restricted means from extrapolation, means from trial or model). The criterion of small population favoured technologies with limited indication (rejection 20%). Earlier TAs presented weight calculations, while later TAs only presented ICERs. **CONCLUSIONS:** Although aiming for greater transparency, the criteria left a large scope for interpretation in the decision making. Also, with the emphasis from applying higher weights to EOL life-years shifting to a differential threshold for certain indications, the original idea of considering wider societal preferences seem to have been neglected, that the new guidance should remedy.

PCN269

APPLICABILITY OF EUNETHTA RELATIVE EFFECTIVENESS ASSESSMENT OF PAZOPANIB FOR NATIONAL ASSESSMENTS

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